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| 10/533,942 | 05/04/2005 | Enrico Garaci | ARC-4865-45 | 9693 | |
| 23117 7590 09242099 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203 | | | EXAM | EXAMINER | |
| | | | ZAREK, PAUL E | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/533 942 GARACI ET AL. Office Action Summary Examiner Art Unit Paul Zarek 1617 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 28 January 2009. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 4-9 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 4-9 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

6) Other:

5) Notice of Informal Patent Application

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

 A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/28/2009 has been entered.

Status of the Claims

 Claims 10-12 have been cancelled by the Applicant in correspondence filed on 01/28/2009. Claims 4-9 are currently pending. This is the first Office Action on the merits of the claim(s) following a request for continued examination.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35
U.S.C. 119(a)-(d). The certified copy of Italian patent application RM2002A000562 (filed on 11/06/2002) has was received on 10/15/2008. The foreign priority of the instant application is 11/06/2002

RESPONSE TO ARGUMENTS

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4 Claims 10-12 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. This rejection is most in light of Applicants' cancellation of Claims 10-12.

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5. Claims 4-9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Heredia, et al. (Journal of Acquired Immune Deficiency Syndromes, 2000) in view of Kurokawa, et al (Journal of General Virology, 1990, and Pätzold, et al. (Antiviral Research, 1993), Applicants traversed this rejection on the grounds that the art cited does not render obvious the claimed invention. Specifically, Applicants allege that Heredia, et al., and Pätzold, et al., teach that resveratrol (Heredia, et al.) or a PKC inhibitor (Pätzold, et al.) inhibit HIV replication, and not influenza replication. Applicants note that HIV and influenza are distinct RNA viruses, possessing different life cycles. Thus, one of ordinary skill in the art would not reasonably expect that a treatment for HIV would necessarily treat influenza, and vice versa. Applicants also allege that Kurokawa, et al., do not teach that inhibiting PKC would inhibit influenza viral growth, and that the mechanism of the inhibitory effect of the PKC inhibitor, H7, on influenza is, or may be related to some as yet unknown property of H7. Examiner finds the Applicants' arguments persuasive. Thus, the rejection of Claims 4-9 under 35 U.S.C. 103(a) as being unpatentable over Heredia, et al., in view of Kurokawa, et al., and Pätzold, et al., is withdrawn.

Below are listed new grounds of rejection that are not necessitated by amendment to the claims.

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Claim Rejections - 35 USC § 103

- The text of those sections of Title 35, U.S.C. 03(a) not included in this action can be found in a prior Office action.
- Claims 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Root, et al. (Journal of General Virology, 2000), in view of Stewart, et al. (Biochemistry, 1999), and Heredia, et al. (above).
- 8. Claims 4 and 7 are drawn to a method of inhibiting influenza virus replication (Claim 4) or treating an influenza infection (Claim 7) comprising administration of resveratrol. Claims 5 and 8 limit the subject to a human and the influenza virus to human influenza virus. Claims 6 and 9 limit the subject to a veterinary animal and the influenza virus to a veterinary virus infection.
- 9. Root, et al., teach that the inhibiting PKC inhibited influenza viral replication and that the "activity of PKC is crucial for influenza virus entry, and may be a target for future antiviral therapy" (pg 2698, paragraph bridging col 1 and 2). Thus, Root, et al., meet the claim limitations of inhibiting influenza viral replication and treating an influenza infection. Root, et al., do not teach the antiviral properties of resveratrol.
- 10. Stewart, et al., teach that resveratrol inhibits PKC (pg 13245, col 1, paragraph 1, lines 1-
- 3). Taken together, Root, et al., and Stewart et al., teach that resveratrol would be an effective anti-influenza agent. Neither Root, et al., nor Stewart, et al., provide a motivation to use resveratrol to inhibit influenza replication or to treat influenza infections in humans or a veterinary animal.

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11. Heredia, et al., teach that resveratrol is a natural "a widely used natural product,"

indicating that it is already safely used, in vivo, and can be obtained at a low-cost (pg 247, col 1,

final paragraph). This would provide motivation for a skilled artisan to utilize for the inhibition

of influenza replication or treating an influenza infection.

12. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the

time the invention was made to use resveratrol, a known PKC inhibitor, which is safe for in vivo

use and can be obtained at a low cost, for the inhibition of influenza replication and treatment of

influenza infection.

Conclusion

13. Claims 4-7 are rejected.

14. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The

examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Rita J. Desai/ Primary Examiner, Art Unit 1625